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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administratio

Dallas District
4040 North Central Expressw
Dallas, Texas 75204-3145

February 11, 2004

Ref: 2004-DAL-WL-10

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Walter J. Humann, President
Osteomed, LP
3885 Arapaho Road
Addison, Texas 75001

Dear Mr. Humann:

FDA inspected your establishment located in Addison, Texas, on September 9-11, 2003. Your firm manufactures bone fixation and surgical devices at this facility as an FDA registered device manufacturer.

The above-stated inspection revealed that devices you manufacture are adulterated under section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements for medical devices which are set forth in the Quality System regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. Significant deviations include, but are not limited to, the following:

1. Failure to maintain complaint files to include or reference the results of the investigation and corrective action taken, as required by 21 CFR 820.198(e)(6) and (e)(7). Specifically, your firm received a number of user complaints of dental bur tip breakage occurring during oral surgical procedures since September 2002.

2. Failure to identify the action(s) needed to correct and prevent recurrence of non-conforming product and other quality problems, as required by 21 CFR 820.100(a)(3). For example, your firm was aware that periodic dental bur tip breakages were reported in clinical use and during internal testing of your inventory, and was later raised as an issue of patient safety in the February 14, 2003, letter sent to your supplier. Your supplier responded that your firm failed to provide design performance specifications or requirements related to bur breakage. Your firm and the supplier have been discussing the issue of bur breakages since April 2002 but have not been able to provide an effective solution to resolve this on-going quality problem reported since 2002.

3. Failure to verify or validate the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device, as required by 21 CFR 820.100(a)(4). To temporarily address a recurring problem of dental bur tip breakages in clinical use, your firm has been [redacted] testing [redacted] of dental burs for tip integrity before releasing them to production since [redacted]. Your firm stated to our investigator that your QC inspectors merely applied a force [redacted] by [redacted] on the tip at an angle to see if the tip snapped. Your firm acknowledged that there was no written and validated test procedure established at the time of our inspection and that this test was neither reliable nor consistent. Your firm has not demonstrated the act of [redacted] the tip will not adversely affect the tip integrity. It should be noted that [redacted] QC testing of a product may not correct a potential design problem or other types of quality problems in the product, and therefore may not provide a long term and an effective quality solution.

4. Failure to validate device design including testing under actual or simulated use conditions as required by 21 CFR 820.30(g). Your firm stated to our investigator that your firm would validate the tip integrity test ([redacted] test) but that this test was neither consistent nor reliable. You may not be able to fully test or measure the durability (quality) of the metal bur tip without first validating the device design specifications. This test method may not reliably detect stress and breakage characteristics of the dental burs experienced under actual clinical use conditions. For example, your firm has not demonstrated that the [redacted] test is equivalent to drilling the bur into a bone structure at various speeds, times, angles, and forces.

5. Failure to establish and maintain procedures to include the requirements, including quality requirements, that must be met by suppliers, contractors, and consultants, as required by 21 CFR 820.50(a). In the March 19, 2003, letter, your supplier stated that your firm failed to provide them with design performance specifications or requirements related to bur breakage or failed to provide them with the actual burs (i.e., broken in the field and some unused burs) in order for them to analyze the product failures, and therefore determine possible corrective actions.

6. Failure to establish and maintain procedures to control product that does not conform to specified requirements, as required by 21 CFR 820.90(a). Specifically, your procedures require an investigation of product nonconformance yet the status or results of the investigation to determine the potential root causes of bur tip breakages occurring during your production testing were not documented on the Nonconforming Material Reports. See NCMR 5410, dated 2/24/03, and NCMR 6029, dated 7/10/03.

Additionally, the inspection revealed that your devices are misbranded under section 502(t)(2) of the Act, in that information was not submitted to FDA as required by the Medical Device Reporting regulation (MDR), 21 CFR Part 803.

1. Failure to file a report of death, serious injury, or malfunction to FDA within 30 calendar days from becoming aware of a reportable event, as required under 21 CFR 803.50. See the definition of a serious injury and malfunction in 21 CFR 803.3(bb)(1) and 803.3(n), respectively.

   a) For example, the following events should have been reported to FDA as MDR reports: Field Experience Report Query, dated 9/9/2003, showed 53 complaints of overheated handpiece drills that have been reported to your firm since 1/2001. Twelve of these complaints described that overheated drills caused contact burns to patients' lips or cheeks. See FDA 483 Item 1. Records attached to FER #020803, event dated 7/23/02, documented that a patient was referred to a plastic surgeon and undergoing a medical treatment for the burn; this event should have been reported as an MDR serious injury.

      i) Another complaint in FER #020805 documented that the patient suffered a first degree burn and was treated.

   b) For example, the following event was not filed within 30 calendar days. Field Experience Report (FER) #021203, event dated 2/13/02, was reported to FDA as a malfunction on September 23, 2003, the report was submitted past the required 30 day reporting time frame and was not submitted as a serious injury. A round bur (Catalog #455-308) had fractured during an oral surgical procedure and was not retrievable during the case. The patient complained of numbness and subsequently underwent an imaging procedure to locate the metal fragment in the patient's mandibular nerve. An additional surgery was performed to remove the metal fragment in order to relieve the pressure on the nerve.

2. Failure to establish and maintain MDR event files to include all documentation of the entity's deliberations and decision making processes used to determine if a device related death, serious injury, or malfunction was or was not reportable, as required by 21 CFR 803.18(b)(1)(i). For example, your field experience reports documented that the complaints involved patient injury. These reports do not include or reference whether any follow-up information had been obtained or had been requested in order to adequately review the complaints and determine the extent of the patient injury and if any medical or surgical intervention was performed. Your firm indicated to our investigator that your staff always orally discussed whether or not an event is reportable even if it was not documented in the complaint file. See an example of the complaints of burned lips or cheeks and dental bur breakages listed in FDA 483 Items 1 and 2. This deficiency in your firm's complaint and MDR handling procedures was found to be a repeat observation from the previous inspection in December 2000.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no applications for premarket approval of Class III devices to which the Quality System regulation deficiencies are reasonably related will be approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be granted until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties.

We are concerned that your firm has not notified the users of the problem with the defective burs so they can take the proper action to mitigate possible risks to patients. Please respond in writing to this concern and provide the justification for not addressing the users. If you decide to notify the users of the problem, please contact Mrs. Sherrie Krolczyk, Recall Coordinator, at 214-253-5222, for instructions and guidance.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Thao Ta, Compliance Officer, Food and Drug Administration, 4040 N. Central Expressway, Suite 300, Dallas, Texas 75204.

Sincerely,

Michael A. Chappell
Dallas District Office

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